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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,734	06/25/2001	Bruce Joseph Roser	GJE-6089D1	2528

23557 7590 03/25/2002  
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GAINESVILLE, FL 326066669

EXAMINER
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PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/25/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/888,734

Applicant(s)

ROSER, BRUCE JOSEPH

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-13 are presented for examination.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Roser (BioPharm 4(8):47-53 (September 1991)) (Roser I).

Roser clearly discloses that trehalose has been used as a preservative agent for Factor VIII in dried form. See p. 52. ("Trehalose, on the other hand, is extremely stable and confers on the product the same resistance to hostile environments enjoyed by cryptobiotic organisms. Similar data have been obtained with a large range of biological molecules, including a panel of monoclonal antibodies against human blood groups and pharmaceutical proteins such as recombinant Factor VIII.") Roser I makes no mention of using albumin with the trehalose. A holding of anticipation is clearly proper.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roser (BioPharm 4(8):47-53 (September 1991)) (Roser I) and Livesey et al (U.S. Pat. 5,364,756) in view of Roser (U.S. Pat. 4,891,319) (Roser II) and Lee et al (EP 0 314 095).

As discussed above, Roser I discloses the use of trehalose in preserving factor VIII in the absence of albumin. Moreover, Livesey discloses the drying of biological materials including Factor VIII (see claim 17) in cryoprotectant solutions comprising trehalose in the absence of serum albumin (see claim 9), wherein the drying is performed at ice-forming temperatures. Although it is not clear that Roser I and Livesey disclose the exact amounts of trehalose and calcium ion claimed, note specifically that Livesey clearly discloses the suitability of

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using calcium-containing buffers in the cryoprotectant methods disclosed therein. Moreover, Lee et al clearly discloses the desirability of using the claimed amount of calcium chloride in buffers for use in lyophilizing factor VIII. Thus, applicant's selection of a concentration of calcium known to be useful in the preservation of factor VIII clearly would have been obvious at the time of applicant's invention. Note specifically Roser I's discussion regarding the requirement of buffers in which the biological molecule is active, at pages 48 and 49. Note further that Lee clearly discloses that Factor VIII is active at the claimed calcium concentration.

Regarding the claimed amount of trehalose, Roser II clearly discloses that the amount of trehalose to be used in preserving biological materials is routinely optimized, depending on the amount of protein present in the sample to be preserved. See col. 3, lines 21-31. Thus, determination of a specific amount of trehalose, including that claimed would have been a routine matter of optimization on the part of the artisan of ordinary skill, and therefore clearly obvious under 35 U.S.C. § 103(a).

Lastly, regarding the reconstitution of the dried materials in saline or water, note specifically that at the time of applicant's invention it was well known that both of these vehicles was suitable for injection, the known method of

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administration of Factor VIII. A holding of obviousness is therefore required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No 4,891,319 (Roser II), in view of Roser (BioPharm 4(8):47-53 (September 1991)) (Roser I) and Livesey et al (U.S. Pat. 5,364,756) and Lee et al (EP 0 314 095).

The claims of the '319 patent (Roser II) clearly recite methods wherein any and all proteins and biological macromolecules are protected against denaturation by drying with

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trehalose. Note specifically the suitability of the method for "enzyme serum" (claim 3 at col. 13), from denaturation. In view of Roser I's and Livesey's disclosure that Factor VIII can be readily preserved according to the methods claimed by the '319 patent, the instant claims are clearly obvious over the previously patented claims, to the extent they recite drying Factor VIII in the presence of trehalose, including at the claimed trehalose concentrations. Further still, the instant claims' recitation of specific amounts of calcium ion are clearly obvious over the '319 patent's claims, in view of Livesey and Lee's disclosure of the suitability of calcium in the trehalose/Factor VIII composition, and particularly in view of Roser I's disclosure of the requirement of buffer components in which the biological material is active.

In sum, the '319 claims' clear disclosure of the suitability of any and all biological materials, including proteins, combined with Roser I's clear disclosure of Factor VIII's amenability to the '319's claimed methods, clearly makes the instant claims obvious over the '319 patent. Moreover, the prior art's disclosure of the desirability of the presence and amounts of the claimed ingredients clearly demonstrates the obviousness of all the claims over applicant's previous '319 patent.

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Claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 08/875,796, in view of Roser (BioPharm 4(8):47-53 (September 1991)) (Roser I) and Livesey et al (U.S. Pat. 5,364,756) and Lee et al (EP 0 314 095). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims' recitation of drying at a temperature of less than 10 degrees C clearly encompasses the freeze drying recited in claim 7 of '796 application. Moreover, the product resulting from the process recited in claim 7 of the '796 application clearly renders obvious the presently claimed products, particularly in view of the Roser, Livesey and Lee references, which suggest the use of salts in the lyophilization buffer. Further still, the use of the lyophilized factor VIII product in reconstituted form, as recited in instant claims 11-13, for injection clearly would have been obvious as injection was the known method of administering factor VIII.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

AS discussed immediately above, claims 1-13 of this application conflict with claim 7 of Application No. 08/875,796.



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37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
March 19, 2002